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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,224

Applicant(s)

NEMOTO, SHIGERU

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/780,731.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

The current status of all nonprovisional parent applications referenced should be included. Specifically, the first sentence of the specification should be amended after "...a divisional of U.S. Patent Application No. 09/708,731, filed February 9, 2001," to include --now Patent No. 6,676,635--. Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed 1/26/04 fails in part to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but some of the information referred to therein has not been considered. Specifically, a copy of GB 1,335,290 has not been provided and is not part of the application file. It is asked that a copy be submitted with the next correspondence.

Specification

The disclosure is objected to because of the following informalities:

1. The Summary of the invention is objected to for not being commensurate with the invention as claimed. Generally, the summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously

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existent in the prior art (and preferably indicated in the Background of the Invention).

The present summary seems to be a listing of claims from the parent application which references the invention as a whole and is not directed to the claimed invention.

2. The Brief Description of the Drawings does not reference all the drawings included in the application. Specifically, brief descriptions of figures 3(a)-(d), 4(a)-(c), 5(a)-(d), 6(a)-(b), 15(a)-(c), 16(a)-(b), 38(a)-(c) and 39(a)-(c) are missing.

Appropriate correction is required.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. The phrase “any of claims 1-4” should read – any one of claims 1-4--.

Claim 2 is objected to because of the following informalities: the claim recites “the cylinder” which does not reference a previously presented limitation of the claims. It is suggested that this recitation be amended to refer to the syringe barrel, i.e. --the barrel-- or --the syringe barrel--, or the limitation of --a cylinder of the syringe barrel-- should be positively introduced in the beginning of the claim. Appropriate correction is required.

Claim 3 is objected to because of the following informalities: the claim recites “the inner wall surface” and “the syringe barrel side” which do not reference previously presented limitations of the claims. It is suggested that these recitations be amended to read as positive limitations, i.e. --an inner wall surface on a syringe barrel side--.

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Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Armbruster et al (USPN 5,322,511). Armbruster discloses an injector that includes a syringe barrel (80) having a flange (92) and a guide (94,96,96' or 94,98,98'). See figures 11-12. Figure 10 shows a groove for the insertion of the flange. Figure 12 shows the flange inserted in the groove. Figure 16 shows the guide (94,98,98') engaging a portion (74) of the cylinder holder. This "lock and key" mechanism will restrict the mounting direction of the syringe barrel. Only the two sides of the flange that have the guide can be positioned within the groove thereby restricting the syringe to two directions of insertion.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Reilly (USPubN 2002/0165491). Regarding claim 1, Reilly discloses a syringe and injector system. The syringe barrel (100) includes a flange (threading 130) and a guide (140). See figure 2A. The term flange is understood to be "a rib or rim for strength, for guiding, or for attachment to another object".

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See <http://www.merriam-webster.com/cgi-bin/dictionary?book=Dictionary&va=flange&x=21&y=19>. Clearly, the threading (130) is a rim of the syringe barrel and is used for attachment to the injector; therefore, the threading (130) is considered a flange.

Regarding the functional language of the claims, applicant is reminded that function language is given limited patentable weight. As long as the prior art meets the structural limitations of the claims and is capable of performing the recited function, the prior art reads on the claimed invention. The flange (130) is adapted to be mounted in a flange insertion groove of a cylinder holder since the flange (130) is an annular rim and is capable of being inserted into an annular groove. Guide (140) is engaged with slot (260) of the cylinder holder (230) and restricts the mounting direction of the syringe barrel. The syringe barrel can only be inserted in an orientation where the guide (140) aligns with the slot. Hence, the guide restricts the mounting direction of the syringe. See figures 2A and 3 and paragraph 42.

Regarding claim 2, as shown in figure 2A, the guide is a projection having a thickness. Figure 3 shows the insertion of the flange (130) into an insertion groove (232) of the cylinder holder (230). However, the guide (140) does not fit within the groove but rather a portion of the cylinder holding having a slot (260) formed adjacent the groove. Due to this “lock and key” construction, the syringe barrel cannot be rotated once inserted within the cylinder holder (230).

Regarding claim 3, the slot (260) has two inner walls which form vertical parts that extend to the surface of the cylinder holder (230) that receives the flange. The guide has two complimentary vertical walls that form a box shape that engages with the vertical walls of the slot (260). See figures 2A and 3 and paragraph 42.

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Also, the syringe has an additional flange (160) that helps to form a secure interference fit between the syringe and the injector to prevent leakage between the syringe and the injector. See paragraph 47.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly in view of Fago et al (USPN 6,569,127).

Reilly meets the claim limitations as described above for claims 1 and 2 but fails to include the cylinder holder comprising two clamps where the two clamps are open before mounting of the syringe barrel and upper parts of the clamps are closed toward the inner side to fix the flange when the syringe barrel is mounted on the cylinder holder.

However, Fago discloses a syringe and injector system that includes a syringe barrel (80) with a flange (82). The syringe is inserted into an injector having a cylinder holder (86). See figure 8. In this embodiment, the cylinder holder (86) has two clamps (90a,90b). See figure 9. The clamps are open before mounting of the syringe. See figure 8. The clamps are closed toward an inner side (toward the syringe barrel) when the barrel is mounted on the cylinder holder. See figure 9. The clamps (90a,90b) are considered to "fix the flange" in securing the barrel thereby securing or fixing the flange when the syringe is mounted on the cylinder holder

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(86). See 8:22-24. The clamps have a dual function to seal the outer wall of the syringe to the injector and to provide mechanical stability. See 8:15-24.

At the time of the invention, it would have been obvious to one skilled in the art to substitute the flange (160) of Reilly with the clamps (90a,90b) of Fago. Both devices are analogous in the art of syringe injection systems and both have front loading syringe barrels; therefore, a combination is proper. Additionally, the flange (160) of Reilly and the clamps (90a,90b) of Fago are functional equivalents designed for the same purpose and to solve the same problem, i.e. prevent fluid leakage between the syringe barrel and the injector. Furthermore, the clamps of Fago have an additional function to provide mechanical stability to the connection of the syringe to the injector. See Fago 8:15-24. This added function enhances the design and performance of the clamp over the flange in reducing the ability of the syringe to become inadvertently removed or dislocated from the injector. The motivation for the incorporation is garnered from the fact that the structures are functional equivalents. Additionally, one skilled in the art would recognize this equivalency and the clamps would be incorporated to achieve the same function in addition to enhancing mechanical stability to the connection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,676,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elements of claim 1 are found in or obvious in light of claims 1 and 7 in the patent.

Claim 1 recites “a syringe barrel for an injection apparatus, the syringe barrel being adapted to be mounted on a cylinder holder that comprises a flange insertion groove” (see lines 1-4 of claims 1 and 7 of the patent); “a flange adapted to be held by said flange insertion groove so as to fix the syringe barrel” (see lines 2-3 of claims 1 and 7 of the patent); “a guide” (see line 6 of claims 1 and 7 of the patent for the limitation of “a concave portion” which is a guide); “which can be engaged with the cylinder holder” (see lines 7-8 of claims 1 and 7 of the patent for the limitation of “engaged with a positioning mechanism installed in the cylinder holder”).

Claim 1 also recites that the guide can “restrict the mounting direction of the syringe barrel”. This is not explicitly recited in either claims 1 or 7 of the patent.

However, one skilled in the art would recognize that the broad function language of claim 1, “restrict the mounting direction of the syringe barrel”, is obvious in light of the patent claim limitations of “a concave portion...engaged with a positioning mechanism”. To engage the concave portion with the positioning mechanism, one would have to directionally align the

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concave portion of the flange with the mechanism of the cylinder holder. This action would thereby restrict the mounting direction of the syringe barrel to the aligned position.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/211,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elements of claim 1 are found in or obvious in light of claim 4. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 recites “a syringe barrel for an injection apparatus, the syringe barrel being adapted to be mounted on a cylinder holder that comprises a flange insertion groove” (see lines 2 and 4-5 of the copending app); “a flange adapted to be held by said flange insertion groove so as to fix the syringe barrel” (see lines 4-5); “a guide” (see line 3); “which can be engaged with the cylinder holder” (see lines 6-9).

Claim 1 also recites that the guide can “restrict the mounting direction of the syringe barrel”. This is not explicitly recited in claim 4 of the copending application.

However, one skilled in the art would recognize that the broad function language of claim 1, “restrict the mounting direction of the syringe barrel”, is obvious in light of the copending application claim limitations of “the guide groove being capable of guiding a guide projection”. To guide the guide projection within the guide groove, one would have to directionally align the guide projection and groove. This action would thereby restrict the mounting direction of the syringe barrel to the position where the projection and groove are aligned.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams

February 4, 2005